



03-05-04

Docket 17637 (BOT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: FIRST, ERIC R.

Serial No.: 10/731,973

Filed: December 9, 2003

For: BOTULINUM TOXIN THERAPY
FOR SKIN DISORDERS

Examiner:

Group Art Unit:

Irvine, California

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant provides with regard to the above-identified patent application entitled BOTULINUM TOXIN THERAPY FOR SKIN DISORDERS, one copy of documents of which he is aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of the documents submitted is set forth on the attached Information Disclosure Citation (Form PTO-1449).


While these documents may be material pursuant to 37 C.F.R. §1.56, the disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material

documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

Date: March 3, 2004


Stephen Donovan
Attorney of Record
Registration Number 33,433

Please direct all inquiries and correspondence to:

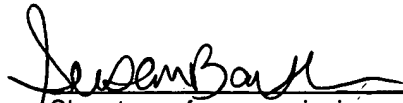
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CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10

I hereby certify that this Information Disclosure Statement and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date March 3, 2004 in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EV193717244US addressed to Mail Stop: Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

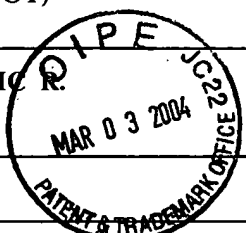
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FILING DATE: 12/9/03	GROUP:



U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	10/194,805		Donovan, Stephen			7/11/2002
	AB	5,437,291	8/1/1995	Pasricha et al.			
	AC	5,670,484	9/23/1997	Binder, William			
	AD	5,714,468	2/3/1998	Binder, William			
	AE	5,766,605	6/16/1998	Sanders et al.			
	AF	5,989,545	11/23/1999	Foster et al.			
	AG	6,063,768	5/16/2000	First, Eric			
	AH	6,139,845	10/31/2000	Donovan, Stephen			
	AI	6,265,379	7/24/2001	Donovan, Stephen			
	AJ	6,299,893	10/9/2001	Schwartz et al.			
	AK	6,306,423	10/23/2001	Donovan et al.			
	AL	6,312,708	11/6/2001	Donovan, Stephen			
	AM	6,358,926	3/19/2002	Donovan, Stephen			
	AN	6,423,319	7/23/2002	Brooks et al.			
	AO	6,458,365	10/1/2002	Aoki et al.			
	AP	6,464,986	10/15/2002	Aoki et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
	BA						

OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

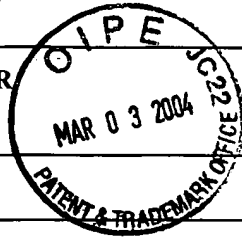
	CA	Andreadis S., et al., <i>Keratinocyte growth factor induces hyperproliferation and delays differentiation in a skin equivalent model system</i> , FASEB J. 2001 Apr;15(6):898-906
	CB	Aoki K., et al, <i>Mechanisms of the antinociceptive effect of subcutaneous Botox: Inhibition of peripheral and central nociceptive processing</i> , Cephalalgia 2003 Sep;23(7):649

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	CC	Arredondo J., et al., <i>Central role of alpha7 nicotinic receptor in differentiation of the stratified squamous epithelium</i> , J Cell Biol. 2002 Oct 28;159(2):325-36
	CD	Asahina A., et al., <i>Specific induction of cAMP in Langerhans cells by calcitonin gene-related peptide: relevance to functional effects</i> , Proc Natl Acad Sci U S A. 1995 Aug 29;92(18):8323-7
	CE	Bigalke H., et al., <i>Botulinum A Neurotoxin Inhibits Non-Cholinergic Synaptic Transmission in Mouse Spinal Cord Neurons in Culture</i> , Brain Research 360;318-324:1985
	CF	Bigalke H., et al., <i>Tetanus Toxin and Botulinum A Toxin Inhibit Release and Uptake of Various Transmitters, as Studied with Particulate Preparations From Rat Brain and Spinal Cord</i> , Naunyn-Schmiedeberg's Arch Pharmacol 316;244-251:1981
	CG	Binz T. et al., <i>The Complete Sequence of Botulinum Neurotoxin Type A and Comparison with Other Clostridial Neurotoxins</i> , J Biological Chemistry 265(16);9153-9158:1990
	CH	Brem, H., et al., <i>Placebo-Controlled Trial of Safety and Efficacy of Intraoperative Controlled Delivery by Biodegradable Polymers of Chemotherapy for Recurrent Gliomas</i> , Lancet 345;1008-1012:1995
	CI	Bushara K., <i>Botulinum toxin and rhinorrhea</i> , Otolaryngol Head Neck Surg 1996;114(3):507
	CJ	Chen W., et al., <i>Trophic interactions between sensory nerves and their targets</i> , Journal of Biomedical Science. 1999;6(2):79-85
	CK	Chiang H-Y, et al., <i>Regional difference in epidermal thinning after skin denervation</i> , Exp Neurol 1998;154(1):137-45
	CL	Chien., et al., (2001) <i>Quantitative pathology of cutaneous nerve terminal degeneration in the human skin</i> , Acta Neuropathologica 102:455-461
	CM	Duggan et al.; <i>A survey of Botulinum neurotoxin substrate expression in cells; Mov Disord</i> , 10(3):376:1995
	CN	Fung L. K. et al., <i>Pharmacokinetics of Interstitial Delivery of Carmustine 4-Hydroperoxycyclophosphamide and Paclitaxel From a Biodegradable Polymer Implant in the Monkey Brain</i> , Cancer Research 58;672-684:1998
	CO	Gonelle-Gispré et al.; <i>Snap -25a and -25b isoforms are both expressed in insulin-secreting cells and can function in insulin secretion; Biochem J</i> 1;339 (pt 1):159-65:1999
	CP	Grando S., <i>Biological functions of keratinocyte cholinergic receptors</i> , J Investig Dermatol Symp Proc. 1997 Aug;2(1):41-8

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	CQ	Grando S., et al., <i>Activation of keratinocyte nicotinic cholinergic receptors stimulates calcium influx and enhances cell differentiation</i> . Invest Dermatol. 1996
	CR	Grando S., et al., <i>Human keratinocytes synthesize, secrete, and degrade acetylcholine</i> J Invest Dermatol. 1993 Jul;101(1):32-6
	CS	Grando S., et al., <i>Keratinocyte muscarinic acetylcholine receptors: immunolocalization and partial characterization</i> , J Invest Dermatol. 1995 Jan;104(1):95-100
	CT	Griffin J., et al., <i>Axonal degeneration and disorders of the axonal cytoskeleton</i> . In: Waxman S., et al., <i>The Axon</i> . New York: Oxford University Press, 1995:375-390
	CU	Habermann E., et al., <i>Tetanus Toxin and Botulinum A and C Neurotoxins Inhibit Noradrenaline Release From Cultured Mouse Brain</i> , J Neurochem 51(2):522-527:1988)
	CV	Habermann E., <i>Inhibition by Tetanus and Botulinum A Toxin of the release of [3H]Noradrenaline and [3H]GABA From Rat Brain Homogenate</i> , Experientia 44:224-226:1988
	CW	Habermann, E.; <i>I-Labeled Neurotoxin from Clostridium Botulinum A: Preparation, Binding to Synaptosomes and Ascent to the Spinal Cord</i> ; <i>Nauny-Schmiedeberg's Arch. Pharmacol.</i> 1974; 281, 47-56
	CX	<i>Harrison's Principles of Internal Medicine</i> (1998), edited by Anthony Fauci et al., 14th edition, published by McGraw Hill
	CY	Hokfelt T., <i>Neuropeptides in perspective : The last ten years</i> , Neuron 1991; 7: 867-879
	CZ	Hosoi J., et al., <i>Regulation of Langerhans cell function by nerves containing calcitonin gene-related peptide</i> , Nature. 1993 May 13;363(6425):159-63
	CAA	Hsieh S., et al., <i>Epidermal denervation and its effects on keratinocytes and Langerhans cells</i> , J Neurocytol. 1996 Sep;25(9):513-24
	CBB	Hsieh S., et al., <i>Modulation of keratinocyte proliferation by skin innervation</i> . Journal of Investigative Dermatology, 1999;113(4):579-86
	CCC	Hsieh S., et al., <i>Pathology of nerve terminal degeneration in the skin</i> , Journal of Neuropathology & Experimental Neurology. 2000;59(4):297-307
	CDD	Hsieh S., et al., <i>Skin Innervation and Its Effects on the Epidermis</i> , J Biomed Sci. 1997;4(5):264-268
	CEE	Huang et al.; <i>Influence of Cutaneous Nerves on Keratinocyte Proliferation and Epidermal Thickness in Mice</i> ; Neuroscience. 1999;94(3):965-73

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	CFF	Inaba N., et al., <i>Capsaicin-induced calcitonin gene-related peptide release from isolated rat stomach measured with a new chemiluminescent enzyme immunoassay</i> , Jpn J Pharmacol. 1996 Nov;72(3):223-9
	CGG	Jankovic J. et al., <i>Therapy With Botulinum Toxin</i> , Marcel Dekker, Inc., (1994), page 5, 150
	CHH	Johnson M., <i>Synaptic glutamate release by postnatal rat serotonergic neurons in microculture</i> , Neuron 1994; 12: 433-442
	CII	Kaneko T., et al., <i>Immunohistochemical demonstration of glutaminase in catecholaminergic and serotonergic neurons of rat brain</i> , Brain Res. 1990; 507: 141-154
	CJJ	Kasakov L., et al., <i>Direct evidence for concomitant release of noradrenaline, adenosine 5'-triphosphate and neuropeptide Y from sympathetic nerve supplying the guinea-pig vas deferens</i> . J. Auton. Nerv. Syst. 1988; 22: 75-82
	CKK	Katsambas A., et al., <i>Cutaneous diseases of the foot: Unapproved treatments</i> , Clin Dermatol 2002 Nov-Dec;20(6):689-699
	CLL	Ko M., et al., <i>Cutaneous nerve degeneration induced by acrylamide in mice</i> , Neuroscience Letters. (2000)293(3):195-8
	CMM	Komuves et al., <i>Epidermal Expression of the Full-Length Extracellular Calcium-sensing Receptor is Required for Normal Keratinocyte Differentiation</i> ; J Cell Physiol. 2002 Jul;192(1):45-54
	CNN	Krnjevic K., <i>Central cholinergic mechanisms and function</i> . Prog Brain Res. 1993;98:285-92
	COO	Kupfermann I.; <i>Functional studies of cotransmission</i> . Physiol. Rev. 1991; 71: 683-732.48: 545-59
	CPP	Lee M., et al., <i>Clinical and electrophysiological characteristics of inflammatory demyelinating neuropathies</i> , Acta Neurol Taiwan 1997;6:283-288
	CQQ	Legat F., et al., <i>Repeated subinflammatory ultraviolet B irradiation increases substance P and calcitonin gene-related peptide content and augments mustard oil-induced neurogenic inflammation in the skin of rats</i> , Neurosci Lett. 2002 Sep 6;329(3):309-13
	CRR	Li Y, et al., <i>Sensory and motor denervation influences epidermal thickness in rat foot glabrous skin</i> , Exp Neurol 1997;147:452-462 (see page 459)
	CSS	Lin Y., et al., (2001) <i>Cutaneous nerve terminal degeneration in painful mononeuropathy</i> , Experimental Neurology. 170(2):290-6

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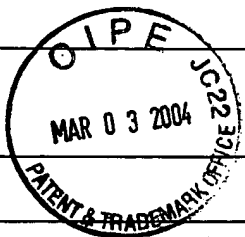
CTT	Lin Y., et al., <i>Quantitative sensory testing: normative values and its application in diabetic neuropathy</i> , Acta Neurol Taiwan 1998;7:176-184
CUU	Lundberg J., <i>Pharmacology of cotransmission in the autonomic nervous system: Integrative aspects on amines, neuropeptides, adenosine triphosphate, amino acids and nitric oxide</i> , Pharmacol. Rev. 1996; 48: 113-178
CVV	McCarthy B., et al., <i>Cutaneous innervation in sensory neuropathies: evaluation by skin biopsy</i> , Neurol 1995;45:1848-1855
CWW	Moyer E et al., <i>Botulinum Toxin Type B: Experimental and Clinical Experience</i> , being chapter 6, pages 71-85 of "Therapy With Botulinum Toxin", edited by Jankovic, J. et al. (1994), Marcel Dekker, Inc.
CXX	Naumann et al.; <i>Botulinum toxin type A in the treatment of focal, axillary and palmar hyperhidrosis and other hyperhidrotic conditions</i> ; European J. Neurology 6 (Supp 4): S111-S1150:1999
CYY	Ndoye A., et al., <i>Identification and mapping of keratinocyte muscarinic acetylcholine receptor subtypes in human epidermis</i> , J Invest Dermatol. 1998 Sep;111(3):410-6
CZZ	Nguyen V., et a., <i>Keratinocyte acetylcholine receptors regulate cell adhesion</i> ; Life Sci. 2003 Mar 28;72(18-19):2081-5
CAAA	Nguyen V., et al., <i>Programmed cell death of keratinocytes culminates in apoptotic secretion of a humectant upon secretagogue action of acetylcholine</i> J Cell Sci. 2001 Mar;114(Pt 6):1189-204
CBBB	Nicholas A. et al., <i>Glutamate-like immunoreactivity in medulla oblongata catecholamine/substance P neurons</i> , NeuroReport 1990; 1: 235-238
CCCC	Palacios J., et al., <i>Cholinergic neuropharmacology: an update</i> , Acta Psychiatr Scand Suppl. 1991;366:27-33
CDDD	Pan C., et al., (2001) <i>Degeneration of nociceptive nerve terminals in human peripheral neuropathy</i> , Neuroreport. 12(4):787-92
CEEE	Pearce, L.B., <i>Pharmacologic Characterization of Botulinum Toxin For Basic Science and Medicine</i> , Toxicon 35(9);1373-1412 at 1393
CFFF	Ragona et al.; <i>Management of Parotid Sialoceles With Botulinum Toxin; The Laryngoscope</i> 109:1344-1346:1999
CGGG	Rogers J., et al., <i>Injections of botulinum toxin A in foot dystonia</i> , Neurology 1993 Apr;43(4 Suppl 2
CHHH	Sanchez-Prieto, J., et al., <i>Botulinum Toxin A Blocks Glutamate Exocytosis From Guinea Pig Cerebral Cortical Synaptosomes</i> , Eur J. Biochem 165;675-681:1997

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	CIII	Schantz, E.J., et al, <i>Properties and use of Botulinum toxin and Other Microbial Neurotoxins in Medicine</i> , Microbiol Rev. 56;80-99:1992
	CJJJ	Sevim, S., et al., <i>Botulinum toxin-A therapy for palmar and plantar hyperhidrosis</i> , Acta Neurol Belg 2002 Dec;102(4):167-70
	CKKK	Singh, <i>Critical Aspects of Bacterial Protein Toxins</i> , pages 63-84 (chapter 4) of Natural Toxins II, edited by B.R. Singh et al., Plenum Press, New York (1976)
	CLLL	Sloop et al.; <i>Reconstituted Botulinum toxin type A does not lose potency in humans if it is refrozen or refrigerated for 2 weeks before use</i> ; Neurology, 48:249-53:1997
	CMMM	Sneddon P., et al., <i>Pharamcological evidence that adenosine triphosphate and noradrenaline are cotransmitters in the guinea-pig vas deferens</i> . J. Physiol. 1984; 347: 561-580
	CNNN	Suputtitada, A., <i>Local botulinum toxin type A injections in the treatment of spastic toes</i> , Am J Phys Med Rehabil 2002 Oct;81(10):770-5
	COOO	Tacks, L., et al., <i>Idiopathic toe walking: Treatment with botulinum toxin A injection</i> , Dev Med Child Neurol 2002;44(Suppl 91):6
	CPPP	Whitehouse P., et al., <i>Nicotinic and muscarinic cholinergic receptors in Alzheimer's disease and related disorders</i> , J Neural Transm Suppl. 1987;24:175-82
	CQQQ	Wiegand et al, I-Labelled Botulinum A Neurotoxin: Pharmacokinetics in Cats after Intramuscular Injection; <i>Nauny-Schmiedeberg's Arch. Pharmacol.</i> 1976; 292, 161-165
	CRRR	Wu T., et al., <i>Demonstration of human papillomavirus (HPV) genomic amplification and viral-like particles from CaSki cell line in SCID mice</i> , J Virol Methods 1997;65:287-298
	CSSS	Xu Z-QD et al, <i>Galanin/GMAP- and NPY-like immunoreactivities in locus coeruleus and noradrenergic nerve terminals in the hippocampal formation and cortex with notes on the galanin-R1 and - R2 receptors</i> , J. Comp. Neurol. 1998; 392: 227-252
	CTTT	Xu Z-QD et al, <i>Galanin-5-hydroxytryptamine interactions: Electrophysiological, immunohistochemical and in situ hybridization studies on rat dorsal raphe neurons with a note on galanin R1 and R2 receptors</i> . Neuroscience 1998; 87: 79-94;
	CUUU	Zia S., et al., <i>Receptor-mediated inhibition of keratinocyte migration by nicotine involves modulations of calcium influx and intracellular concentration</i> , J Pharmacol Exp Ther. 2000 Jun; 293(3):973-81

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